Newborn Screening
Laboratory (615) 262-6352
Results and Follow-Up (615) 262-6304

I. Introduction

Tennessee law requires that a blood sample shall be obtained from each infant born in the state, regardless of age, before discharge from the hospital and tested for specific genetic disorders. These genetic disorders can cause mental retardation or death if not treated quickly. To prevent the early affects of these disorders, the blood sample should be drawn from the infant 24 hours after birth and less than 2 days of life (24-48 hours from birth is the optimum window for sample collection.) Infant's who are screened before they are 24 hours of age must be rescreened within 24 to 48 hours by a local health department, or private physician. Infant's who are born in a non-hospital setting must be taken to a hospital, local health department, or private physician between 24 and 48 hours of birth to have the blood sample collected. Drops of blood from the infant's heel are absorbed into a special filter paper attached to the Newborn Screening Form PH-1582 and sent to the Newborn Screening Laboratory at the Tennessee Department of Health (TDH) Laboratory Services. The current protocol includes testing the blood sample for the following disorders:

PHENYLKETONURIA (PKU)

Infants with PKU lack an enzyme called phenylalanine hydrolase, which is needed to breakdown part of the protein in food. This protein part is called phenylalanine, and unless the condition is detected and treatment is initiated soon after birth, phenylalanine builds up in the blood and body tissues causing mental retardation. Infants are placed on a lifelong special diet low in phenylalanine, which can prevent mental retardation and other effects of PKU. Testing began in 1968 for this disorder, which has an incident rate of 1:12,000 infants.

CONGENITAL HYPOTHYROIDISM (TSH)

Hypothyroidism occurs when the body does not produce enough thyroid hormone from the thyroid gland. This hormone is called thyroxine, which is needed for brain and body growth. A decreased amount of thyroxine can interfere with normal growth and can lead to mental retardation. If detected early and hormone replacement is initiated, normal growth and development can take place. Testing began in 1980 for this disorder, which has an incident rate of 1:4,500 infants.

HEMOGLOBINOPATHIES

Hemoglobin is the part of red blood cells that carries oxygen. Hemoglobinopathies are diseases that affect the kind or amount of hemoglobin a person has in the red blood cells. Some hemoglobinopathies can cause anemias or thalassemias.

Infants of **Asian** or Mediterranean background, such as Italian, Greek, Arab, or Kurdish, should be rescreened for thalassemias at the 12-month routine child-health visit. These specimens can be sent to the Meharry Sickle Cell Center or other laboratory.

Sickle cell disease is the most common hemoglobinopathy. The red blood cells are sticky and crescent or sickle-shaped and therefore do not move easily through the vascular system, decreasing the vital levels of oxygen carried throughout the body. There is a dramatic decrease in infant mortality and life-threatening complications when an infant is identified early and treated with antibiotics. Testing began in 1988 and the incidence rate is 1:350 in the Africa-American population. People of Hispanic, Asian, Arabic, or Mediterranean decent are also more likely to have hemoglobinopathies.

GALACTOSEMIA (GAL)

Infants with galactosemia lack an enzyme, uridyl transferase, needed to breakdown galactose, a kind of major sugar found in milk. Due to either an absent or low enzyme, galactose accumulates in the body leading to mental retardation, growth deficiency, blindness, overwhelming infection and death. Infants with galactosemia can rapidly become sick after only a few days of normal feeding. Infants who are detected early are placed on a lifelong special galactose-free diet. Testing began in 1992 for this disorder which has an incident rate of 1:60,000 infants.

CONGENITAL ADRENAL HYPERPLASIA (CAH)

In order for this test to be reported accurately it is imperative that the **CURRENT weight** of the infant be recorded correctly on the Newborn Screening Form. This disorder results from a deficiency in one or another of the enzymes of steroid syntheses. The deficiency results in an abnormal accumulation of hormones important for normal growth and development of puberty. Most affected infants have a second defect that affects normal electrolyte balance. Infants having this deficiency can become very sick within 1 to 2 weeks of birth. Female infants with this disorder may be assigned the wrong sex at birth. Male infants are often not identified until they are in crisis. With early diagnosis and treatment it is possible to achieve normal growth and development of puberty. Because this disorder is complex, infants may need to be monitored by a pediatric endocrinologist. Testing began in 2000 for this disorder and has an incident rate of 1:10,000 to 1:15,000 infants.

BIOTINIDASE DEFICIENCY

This disorder is caused by the lack of an enzyme in the baby's body called biotinidase. Babies with Biotinidase Deficiency can have seizures, skin rash, or infection, developmental delays and hearing loss. Problems with the disorder can be prevented with treatment using biotin. Testing began in 2003 for this disorder which has an incident rate of 1:70,000 infants.

AMINO ACID DISORDERS

Amino acid disorders are a group of conditions in which there is a problem with breaking down certain components of food called amino acids. These disorders are caused by a specific defect in one of the many enzymes that perform these tasks. The specific amino acid can build up in the blood and other organs, including the brain. This amino acid and any of its metabolites can cause serious health problems such as mental retardation, damage to vital organs, seizures or coma. The effects of the disorder will vary, and depend on the age at which symptoms occur and the specific amino acid(s) elevated. Treatments vary and may include special dietary intervention, replacement medications, acute illness protocols, and metabolic genetic and nutritional monitoring.

ORGANIC ACID DISORDERS

Organic acid disorders are a group of conditions in which there is a problem with breaking down protein and amino acids in foods. This is due to a specific defect in one of the enzymes that breaks down these substances. These organic acids can build up in blood and urine, and can lead to problems such as low blood sugar, failure to thrive, developmental delays, infections and in rare occasions coma and death. The effects of the disorder will depend on the age at which symptoms occur. Delay in the recognition and treatment may have serious consequences. Treatment may include special dietary intervention, replacement medications, acute illness protocols, and metabolic genetic and nutritional monitoring.

FATTY ACID OXIDATION DISORDERS

Fatty Acid Oxidation Disorders are a group of conditions that affect the breakdown of certain fats called fatty acids. A defect in a specific enzyme leads to a build up of fatty acids in the body. When a baby with one of these conditions "fasts" (goes for a long period of time without eating), problems can happen. This occurs because the baby cannot use the energy stored in the fats of the body. This kind of metabolic crisis can sometimes lead to seizures, failure to breathe, cardiac arrest, and death. It is extremely important to identify a child with this disease so that crisis can be prevented. Treatment may include avoiding fasting, replacement medications, monitoring the diet for specific metabolic nutritional requirements and blood levels of certain metabolites.

II. Test Methods

- Galactosemia testing is performed by enzymatic fluorometric methods. A semi-automated fluorescent test is performed on all borderline and abnormal galactosemia results to detect the uridyl transferase enzyme activity. Enzyme activity is reported as numeric values.
- Thyroid testing is performed by a fluoroimmunoassay (FIA) method which detects the amount of thyroid stimulating hormone (TSH) present.
- Hemoglobin testing is performed by High Performance Liquid Chromatography (HPLC).
- Congenital adrenal hyperplasia employs a fluoroimmunoassay (FIA) methodology, which detects the amount of 17α-hydroxyprogesterone (17-αOHP).
- Organic Acid, Fatty Acid and Amino Acid tests are performed by Tandem Mass Spectrometry. These analytes are detected by their mass to charge ratio value.

III. Specimen Collection

A. Collection Form

Use the Newborn Screening Collection Form PH-1582. Forms are available from your local county health department. Health departments can order more forms from the Shipping Department of Laboratory Services. (See Page IV - 27 for the TDH REQUISITION FOR LABORATORY SUPPLIES FORM.) The expiration date of the filter paper is printed near the bottom right corner of the form in red ink. It will have the month/year. Forms are good until the last day of the month printed on the form for the year specified. (Example: EXP. 8/2000 means do not use the form after 8/31/00.) Blood collected on forms after the expiration date will be reported out as "*Unsatisfactory Filter Paper Expired*" and another specimen will have to be submitted.

B. Important Information

1. Infants more than 6 months old

   The test methods used by the Newborn Screening Laboratory are *not suitable for infants greater than 6 months of age*. If the infant is greater than 6 months of age, contact the Metabolic Center closest to the provider to inquire as to what tests need to be performed and where to send the specimens.

2. Procedures When Infants Are Transfused Prior to the Newborn Screening *

   If possible, collect a specimen for the newborn screen **before a transfusion** even if the infant is less than 24 hours of age. The hemoglobin and biotinidase will be accurate, and if it is normal, there is no need for follow-up hemoglobin testing.

   The PKU, TSH, CAH, Total GAL, FA, OA, Biotinidase, and AA test methodologies and results (i.e. measurement of the metabolite) can be affected by transfusions. Any infant that was transfused within 72 hours prior to specimen collection with any of the following blood products will need to have their screen repeated:

   Exchange transfusion
   ECMO procedure
   Whole blood
   Plasma

   GAL, FA, OA, AA and Hemoglobinopathy results can be affected by red blood cell transfusions.

   Biotinidase, FA, OA, and AA results can be affected by platelet transfusions.

   * If an infant has symptoms such as vomiting, diarrhea, dehydration, or jaundice, the newborn screen should be repeated immediately regardless of the number of days that have passed since the transfusion. In addition, the regional metabolic center or endocrinologist (depending on symptoms) should be contacted.

Repeat PKU, TSH, and CAH between 4 and 14 days after transfusion. **Repeat GAL and Biotinidase** between 10 and 90 days after transfusion.

Collect a specimen for PKU, TSH, CAH, MCAD, OA, FA, AA, and Biotinidase, Homocystinuria, and GAL as soon as possible after the tenth day post transfusion. Send the specimen to the TDH Newborn Screening Laboratory.

Repeat Hemoglobinopathy at three months post transfusion. Send the specimen to Meharry Sickle Cell Center. See Newborn Screening Section XIII for information about submitting specimens to Meharry Sickle Cell Center.

If the infant has been transfused, mark transfusion on the collection form and give the last transfusion date.

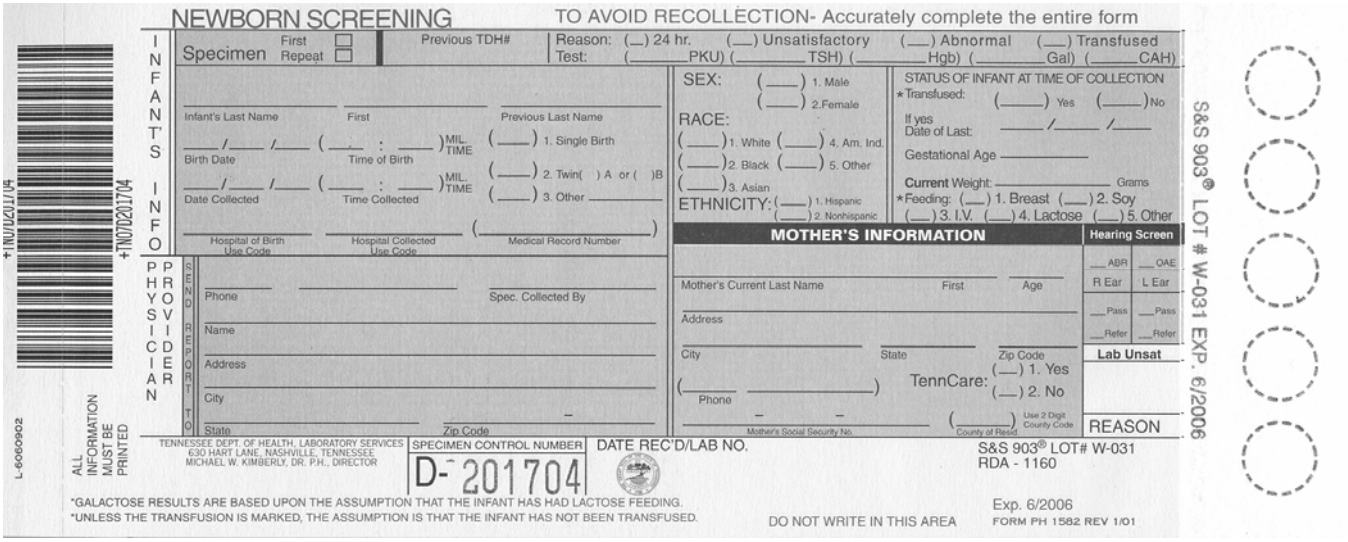
3. Infants in the NICU and Preemies

   Sick or premature newborns should have a specimen collected on or near the seventh day of age regardless of feeding status or before transfusion. PKU results are based upon the assumption the infant has had protein feed. Galactosemia results are based on the assumption the infant is on a lactose feeding. If the infant is sick or not feeding well and the physician feels a test is not accurate due to the infant's feed status, the physician is encouraged to obtain a repeat specimen. If an infant is on soy formula, the provider can request an enzyme to be done by writing "DO ENZ" next to the Gal test on the collection form.

C. Instructions for Filling out the Newborn Screening Form PH-1582 (Revised 2/00)

It is important to fill in all of the blank lines on the form completely, legibly, and accurately. Use a ballpoint pen to legibly print the information on the form. If critical areas on the form are left blank the Women's Health and Genetics Follow-up Section will have to call to obtain the information. This may cause a delay in reporting results.

FRONT


NEWBORN SCREENING

TO AVOID RECOLLECTION- Accurately complete the entire form

INFANT'S INFO

Specimen First ☐ Repeat ☐ | Previous TDH# | Reason: (__) 24 hr. (__) Unsatisfactory (__) Abnormal (__) Transfused
Test: (_____PKU) (_____TSH) (_____Hgb) (_____Gal) (_____CAH)

Infant's Last Name | First | Previous Last Name

Birth Date | Time of Birth (MIL. TIME) | (__) 1. Single Birth

Date Collected | Time Collected (MIL. TIME) | (__) 2. Twin( )A or( )B | (__) 3. Other

Hospital of Birth Use Code | Hospital Collected Use Code | Medical Record Number

SEX: (__) 1. Male (__) 2.Female

RACE: (__)1. White (__) 4. Am. Ind. (__)2. Black (__) 5. Other (__)3. Asian

ETHNICITY: (__) 1. Hispanic (__) 2. Nonhispanic

STATUS OF INFANT AT TIME OF COLLECTION
*Transfused: (_____) Yes (_____) No
If yes Date of Last: ____/____/____
Gestational Age _____
Current Weight: _____ Grams
*Feeding: (__) 1. Breast (__) 2. Soy (__) 3. I.V. (__) 4. Lactose (__) 5. Other

PHYSICIAN / PROVIDER / SEND REPORT TO

Phone | Spec. Collected By

Name

Address

City | State | Zip Code

MOTHER'S INFORMATION

Mother's Current Last Name | First | Age

Address

City | State | Zip Code

Phone | Mother's Social Security No. | County of Resid. | Use 2 Digit County Code

TennCare: (__) 1. Yes (__) 2. No

Hearing Screen: __ABR __OAE | R Ear L Ear | __Pass __Pass | __Refer __Refer

Lab Unsat

REASON

ALL INFORMATION MUST BE PRINTED

L-6060902

TENNESSEE DEPT. OF HEALTH, LABORATORY SERVICES
630 HART LANE, NASHVILLE, TENNESSEE
MICHAEL W. KIMBERLY, DR. P.H., DIRECTOR

SPECIMEN CONTROL NUMBER D- 201704

DATE REC'D/LAB NO.

S&S 903® LOT# W-031
RDA - 1160

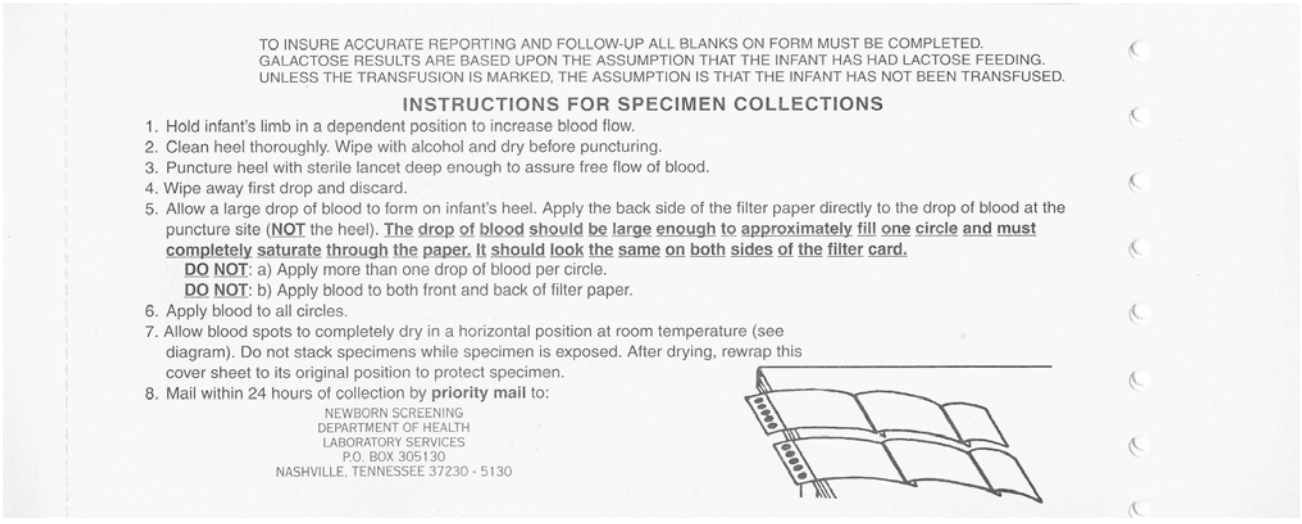
*GALACTOSE RESULTS ARE BASED UPON THE ASSUMPTION THAT THE INFANT HAS HAD LACTOSE FEEDING.
*UNLESS THE TRANSFUSION IS MARKED, THE ASSUMPTION IS THAT THE INFANT HAS NOT BEEN TRANSFUSED.

DO NOT WRITE IN THIS AREA

Exp. 6/2006
FORM PH 1582 REV 1/01

S&S 903® LOT # W-031 EXP. 6/2006

BACK


TO INSURE ACCURATE REPORTING AND FOLLOW-UP ALL BLANKS ON FORM MUST BE COMPLETED.
GALACTOSE RESULTS ARE BASED UPON THE ASSUMPTION THAT THE INFANT HAS HAD LACTOSE FEEDING.
UNLESS THE TRANSFUSION IS MARKED, THE ASSUMPTION IS THAT THE INFANT HAS NOT BEEN TRANSFUSED.

INSTRUCTIONS FOR SPECIMEN COLLECTIONS

1. Hold infant's limb in a dependent position to increase blood flow.
2. Clean heel thoroughly. Wipe with alcohol and dry before puncturing.
3. Puncture heel with sterile lancet deep enough to assure free flow of blood.
4. Wipe away first drop and discard.
5. Allow a large drop of blood to form on infant's heel. Apply the back side of the filter paper directly to the drop of blood at the puncture site (**NOT** the heel). **The drop of blood should be large enough to approximately fill one circle and must completely saturate through the paper. It should look the same on both sides of the filter card.**
   DO NOT: a) Apply more than one drop of blood per circle.
   DO NOT: b) Apply blood to both front and back of filter paper.
6. Apply blood to all circles.
7. Allow blood spots to completely dry in a horizontal position at room temperature (see diagram). Do not stack specimens while specimen is exposed. After drying, rewrap this cover sheet to its original position to protect specimen.
8. Mail within 24 hours of collection by **priority mail** to:

NEWBORN SCREENING
DEPARTMENT OF HEALTH
LABORATORY SERVICES
P.O. BOX 305130
NASHVILLE, TENNESSEE 37230 - 5130

1. Infant's Information

a. Specimen **First** ☐
Repeat ☐

If this is the "first" specimen ever collected on the infant, place a mark in the "First" box. If the infant has previously had a newborn screen performed, at any time, then mark the "Repeat" box.

b. Previous TDH#

If this is a repeat test and the provider or the parent was sent a letter indicating that the specimen should be repeated, write the 11 digit unique TDH number included in the letter in this space. If possible enclose a copy of the letter with the repeat specimen.

c. Reason: (_) 24 hr. (_) Unsatisfactory (_) Abnormal (_) Transfused

If this is a repeat test and the provider or the parent was sent a letter indicating that the specimen should be repeated, a reason would be given on the letter.

If the first specimen was collected before the infant was 24 hours of age and this is why the repeat is being done, mark **(X) 24 hr.**
If the specimen was unsatisfactory for any reason and this is why the repeat is being done, mark **(X) Unsatisfactory**.
If the specimen had an abnormal test result and this is why the repeat is being done, mark **(X) Abnormal**.
If the specimen was collected after the infant was transfused and this is why the repeat is being done, mark **(X) Transfused**.

d. TEST: (__ PKU) (__ TSH) (__HGB) (__GAL) (__CAH)

If you marked the "Reason" as <24, place a mark next to the following test names: PKU, TSH, GAL, and CAH.
If the reason was Unsatisfactory, place a mark next to the following test names: PKU, TSH, HGB, GAL, and CAH.
If the reason was Abnormal, place a mark next to the name of the test that was reported as Abnormal.
If the reason was Transfused, place a mark next to the name of the test that was reported as transfused. See information regarding transfusions on Page IV - 3.
If the specimen is marked as a "First" specimen all test are automatically performed.
If the physician or healthcare provider has requested an Enzyme on the Galactose, write in the (__GAL) blank "DO ENZ". Example: (DO ENZ GAL).

Newborn Screening (Continued)

e. Infant's Last Name:

Legibly print the infant's last name.

f. Infant's First Name:

If the infant has a first name, print it legibly here. If the infant does not have a first name at the time of collection and it was a single birth, write "BOY" for the first name if it's a male infant or "GIRL" for the first name if it is a female infant. If there are multiple births also indicate the birth order by using A, B, C, etc. EXAMPLE: GIRL "A", BOY "B", GIRL "C", BOY "D".

g. Previous Last Name:

If the infant has had a change in their last name, legibly print their previous last name here. *This is very important!* Without this information we are unable to identify when an infant has had a repeat specimen collected.

h. Birth Date:

The day the infant was born. Write the date as MM / DD / YY. The date should be the same day as recorded on the infant's birth certificate.

i. Time of Birth:

The time the infant was born in military time. (See Page IV - 23 for a MILITARY TIME CONVERSION CHART.)
Example: Write 3:00 AM as 0300 and 3:00 PM as 1500. The use of strict military time will indicate AM or PM. The time should be the same time as recorded on the infant's birth certificate.

j. Date Collected:

This is the date the specimen was collected. Write the date as MM / DD / YY.

k. Time Collected:

The time the specimen was collected in military time. (See Page IV - 23 for a MILITARY TIME CONVERSION CHART.) Example: Write 6:00 AM as 0600 and 6:00 PM as 1800. The use of strict military time will indicate AM or PM.

l. Birth Status:

If the infant was a single birth, mark (X) 1. Single Birth. If the infants were twins mark (X) 2. Twin, and mark either ( ) A for the first born or ( ) B for the second born. If the delivery is triplets (or more), mark (X) 3. Other, followed by the number and letter to indicate the birth order. Example: Triplets would be written as 3A, 3B, and 3C. Quadruplets would be written as 4A, 4B, 4C, and 4D.

m. Hospital of Birth and Hospital Collected:

THE REPORT WILL BE MAILED TO THE HOSPITAL OF COLLECTION. Enter the seven-digit hospital code that indicates the location of the infant's birth and the collection hospital. The hospital code is available from the hospital of birth. This blank **must be completed** regardless of the provider. Private physicians and county health departments must also give the code for the hospital of birth on **each specimen submitted to the TDH Laboratory**. If the infant has been transferred, the hospital of collection may be different from the hospital of birth. **Make sure you have the correct codes for both hospitals**.

If the infant was not born in a Tennessee hospital, indicate the location by giving the name and location of the hospital of birth.

If the infant was not born in a hospital, enter the two-digit code for the county and record "HOME" in hospital block as shown. See Page IV-24 for a COUNTY CODE LIST FOR TENNESSEE. (For example Shelby County - Home Birth - |7|9| |H|O|M|E|.)

n. Medical Record Number:

Give the unique patient number assigned to the infant in the hospital, doctor's office, or local health agency.

o. Sex:

If the infant is a boy mark (X) 1. Male. If the infant is a girl mark (X) 2. Female.

p. Race:

Place a mark next to the category which best reflects the race of the infant (_) 1. White, (_) 2. Black, (_) 3. Asian, (_) 4. American Indian, or (_) 5. Other.

q. Ethnicity:

Place a mark next to the category which best reflects the ethnicity of the infant (_) 1. Hispanic, or (_) 2. Nonhispanic.

r. Status of the infant at time of collection:

Transfused: If the infant was not transfused mark (X) No.
If the infant was transfused, in utero or after delivery, mark (X) Yes and then enter the ***last date*** of transfusion (MM / DD / YY) prior to the specimen being collected. The transfusion information must be recorded accurately so that the hemoglobinopathy, galactosemia, and other test results are accurate. (NOTE, see Transfusion Update Memo, page IV-33)

Current Weight: ***NOTE*** Give the weight of the infant at the time the specimen was collected. The current weight of the infant must be recorded accurately so the CAH test results are accurate. The weight must be recorded in grams. See Chart IV - 2 POUNDS AND OUNCES TO GRAMS CONVERSION.

Gestational age _____

Feeding: Place a mark next to the method by which the infant is currently being fed (_) 1. Breast, (_) 2. Soy, (_) 3. Intra Venous, (_) 4. Lactose, (_) 5. Other.

2. Physician or Provider Information

The report will be mailed to the Physician or Provider listed here. The report will also be mailed to the hospital of collection.

a. Phone:

Legibly print the area code and phone number of the physician or health care provider to be contacted if there is an abnormal test result.

b. Spec. Collected By:

Legibly print the name of the individual collecting the specimen.

c. Name:

Legibly print the first and last name of the physician or heath care provider.

d. Address, City, State, and Zip Code:

Legibly print the complete street address, city, state, and zip code + 4 of the physician or health care provider.

3. Mother's Information

Adoption: If a newborn has been adopted please write "ADOPTION CASE" on the form and put either the adoptive parents or the adoption agency's information in the spaces under Mother's Information. If a repeat specimen is required, letters will be sent to the mother listed on the form until the Newborn Screening lab receives a repeat specimen.

a. Mother's Current Last Name:

Legibly print the mother's legal last name.

b. First Name:

Legibly print the mother's legal first name.

c. Age:

Legibly print the age of the mother at the time of the infant's birth.

d. Address, City, State, Zip Code:

Legibly print the mother's complete address where she is currently living including the city, state, and zip code + 4. If the mother's residence is not in the USA, name the country.

e. Phone Number:

Legibly print the area code and home phone number where the infant's mother can be contacted. If the mother does not have a phone, give the area code and phone number of a relative or neighbor who could easily contact the mother.

f. TennCare:

If the mother has TennCare, mark (X) Yes. If the mother has any other type of insurance mark (X) No.

g. Mother's Social Security Number:

Legibly print the mother's social security number.

h. County of Residence:

Legibly print the two-digit code that corresponds to the county in which the mother resides. (See Page IV - 24 for the COUNTY CODE LIST FOR TENNESSEE.)

4. Hearing Screen

Note: If you are only reporting hearing screens, **do not** use the newborn screening forms. Contact Jacque Cundall at 615-262-6160 for instructions regarding the correct method to report and for additional questions regarding the hearing screens.

Hospitals that provide newborn hearing screening utilizing the physiologic methods of ABR and/or OAE are requested to complete the Hearing Screen portion of the form. If your hospital does not provide newborn hearing screening, leave the spaces blank.

Place a mark next to _ABR if the infant was tested by the Auditory Brainstem Response (ABR) or Automated Auditory Brainstem Response (AABR) method. Place a mark next to _OAE if the infant was tested by the Otoacoustic Emissions (OAE) using the Distortion Product Otoacoustic Emissions (DPOAE) or the Transient Evoked Otoacoustic Emissions (TEOAE) method. If both methods were used, mark the method administered prior to discharge and the results.

Ear Screened: Place a mark next to _R Ear if the right ear was screened. Place a mark next to _L Ear if the left ear was screened. Mark both spaces if both ears were screened.

Pass is the term used for a test that indicates the hearing is within normal limits. If the infant passed the test, place a mark next to _Pass. Refer is the term used for referral of infants for further evaluation. If the infant needs to be referred, place a mark next to _Refer.

5. Date Rec'd/Lab No (White area at bottom of form)

DO NOT WRITE IN THIS AREA

The laboratory will record the date and assign a specimen number to the specimen when it is received at the laboratory.

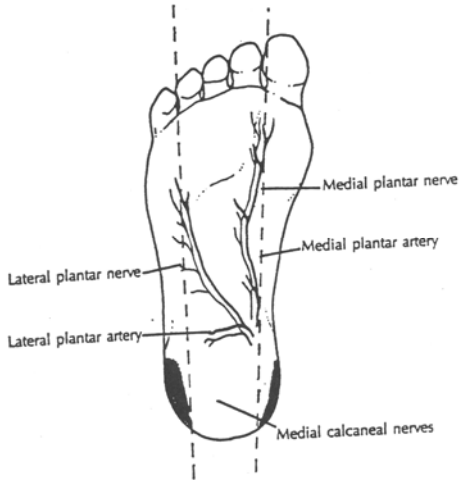
D. Filter Paper Collection Procedure

PRECAUTIONS:

Improper storage of the collection forms can result in the filter paper being altered by the absorption of ambient moisture in the atmosphere, or by compressing the filter paper if they are stacked on top of each other. Store the forms on their side in a cool, clean, dry place. Touching the filter paper, either before or after collection, with gloved or ungloved hands or substances such as powder, hand lotion, feeding formulas, or other materials can alter the filter paper and also the test results. Use of highlighters on the filter paper or wearing strong perfumes may also interfere with testing procedures.

Verify the patient information on the specimen collection form with the infant's identification band, and appropriate chart records before sticking the infant. Check the expiration date of the form. If it has expired do not use it. Appropriate biohazard precautions should be used. Wear powder free gloves and change gloves between infants. Never reuse lancets; place them in a puncture proof sharps container after use. Place biohazardous material in appropriate containers.

1. Select the puncture site on the heel. The shaded areas on the diagram indicate the preferred and least hazardous puncture sites. Draw an imaginary line between the fourth and fifth toes that runs parallel to the lateral aspect of the heel or a line running from the great toe that runs parallel to the medial aspect of the heel.



2. Warming the heel with a warm (Temperature not to exceed 42 °C) wet towel or diaper or a commercially available heel warmer for not more that 3 minutes along with positioning the leg lower than the heart may dilate the blood vessels and therefore increase blood flow.

3. Disinfect the skin with 70% isopropyl alcohol and allow it to air dry. Vigorous rubbing may also stimulate blood flow to the area.

4. Puncture the skin with one continuous motion using a sterile automated lancet. On a full term infant the depth of the puncture should not exceed 2.0 mm. On premature or small infants the puncture should be less than 2.0 mm. Lancets with tips longer than 2.5 mm may cause excessive tissue damage, bone damage, or long term problems with walking.

5. Wipe away and discard the first drop of blood since it may be contaminated by alcohol or tissue fluid.

6. Allow the second drop (approximately 75-100 μl) to form by the spontaneous free flow of blood.

7. Touch the filter paper to the drop of blood as close to the center of the circle as possible. Allow the blood spot to expand within the circle and soak through to the other side. Turn the card over to make sure that the blood did soak through completely. DO NOT press or touch the filter paper to the puncture site.

a. Apply blood to only one side of the filter paper. It does not matter which side, however, the blood must soak through from one side to the other.

b. It is essential that only one drop of blood be used to fill a circle. If the circle cannot be filled with only one drop, go on to the next circle. Do not apply two drops to the same circle.

c. It is permissible for the blood to go outside the circles lines, but do not allow it to overlap on blood in an adjacent circle. Overfilling of the circle can cause supersaturation.

d. Do not use capillary tubes or syringes to fill circles. Such devices may alter the filter paper by scratching it, cause supersaturation, or blood clots.

e. Recollect the sample if tiny blood clots appear on the specimen or if any fluid or substance contaminates the specimen.

8. Once the blood collection is completed, hold the infant's foot above the heart level and press a sterile gauze to the puncture site until the bleeding has stopped. Adhesive bandages are not recommended.

9. Air dry the blood specimen horizontally at room temperature away from heat or direct sunlight for at least 3 hours. Do not allow the blood spots to touch any surface. Do not close the fold-over-paper protective flap for at least 3 hours and the specimen is completely dry.

IV. Shipment of Specimens

After the specimen has had time to dry for at least 3 hours, close the protective paper flap over the top of the blood spots**. DO NOT tape the flap closed or fold the form**. The biohazard label should be placed on the outside of the flap of the form Place the form in a **paper** envelope labeled "Dried Clinical Specimen".. If you are sending more that one form, rotate the forms 180° so that the blood spots are not stacked directly over one another but are alternated. **DO NOT place the forms in any form of a plastic sealed bag.** This includes poly bags, ziplock bags, plasticene envelopes, or plastic shipping bags.

Mail or transport the specimen to the Tennessee Department of Health's Laboratory in Nashville within 24 hours of collection.

If the specimens are going to be mailed **United States Postal Service Address:**	**If the specimens are going to be delivered by Courier, FedEx, or UPS:**
Newborn Screening Tennessee Department of Health Laboratory Services P. O. Box 305130 Nashville, TN 37230-5130	Newborn Screening Tennessee Department of Health Laboratory Services 630 Hart Lane Nashville, TN 37216-2006

The U. S. Postal Service address is what appears on the back of the yellow fold-over flap. If you have your specimens sent by FedEx, UPS or another delivery company you must use the address on the right above.

V. Reporting Procedure and Interpretation

The results of all specimens are reported to the hospital that collected the specimen and the physician or provider listed on the form. If you need a copy of a Newborn Screening Report and your hospital or physician was not listed on the original form, you will need to submit a Release of Records request form signed by the legal parent or guardian. See Page IV - 26 for the REQUEST FOR RELEASE OF RECORDS FORM.

The laboratory reports all positive, or suspected positive, results to Maternal and Child Health, generally within 1 to 2 working days after the specimen is received in the laboratory. Women's Health and Geneticsthen notifies the provider by telephone to initiate treatment of the patient, confirmation testing, and follow-up of the patient. The written report is mailed within 7 to 10 working days after receipt of the specimen.

Written reports of normal specimens are mailed within 7 to 10 working days after receipt in the laboratory.

All unsatisfactory specimens are tested, even though the integrity of the specimen is in question. If a positive, or suspected positive, is found, results are reported to Maternal and Child Health, so that the provider can be notified and treatment can be initiated. **However, all unsatisfactory specimens are reported as unsatisfactory and must be repeated.**

Reference Ranges
Cut-offs points are established through population-based studies.
These values may change over time.

Phenylketonuria (PKU)

< 4.0 mg/dl Within Normal Limits
4.0 – 5.9 mg/dl Borderline
6.0 mg/dl or greater Positive

Galactosemia (GAL)

Positive Enzyme and a Total Gal < 15.0 mg/dl Within Normal Limits
Positive Enzyme and a Total Gal ≥ 15.0 – 19.9 mg/dl Borderline
Positive Enzyme and a Total Gal 20.0 mg/dl or greater Abnormal
Low Enzyme and a Total Gal ≥ 7.0 - < 15.0 mg/dl BorLow
Low Enzyme and a Total Gal ≥ 15.0 mg/dl AbLow
Absent Enzyme and a Total Gal ≥ 5 mg/dl AbNeg

It is assumed that the infant has had a lactose feeding and has not been transfused unless otherwise indicated on the Newborn Screening Collection Form.

Congenital Hypothyroidism (TSH)

For infants 1 day through 7 days
< 33 μU/ml serum Within Normal Limits
33 – 55 μU/ml serum Borderline
> 55 μU/ml serum Positive
For infants 8 days through 6 months of age
< 13 μU/ml serum Within Normal Limits
≥ 13 μU/ml serum Positive
For infants <24 hours of age
< 33 μU/ml serum Within Normal Limits but MUST REPEAT FILTER TEST
≥ 33 μU/ml serum Inconclusive Results MUST REPEAT FILTER TEST

Hemoglobinopathy

FA is a normal hemoglobin pattern for a young infant
AF is a normal hemoglobin pattern for an old infant
The result is reported as Within Normal Limits as long as no abnormal bands are detected.
It is assumed that the infant has not been transfused unless otherwise indicated on the Newborn Screening Collection Form.

Congenital Adrenal Hyperplasia (CAH)

Birth Weight	
<1250 grams	<135 ng/mL
1251-1750 grams	<90 ng/mL
1751-2245 grams	<65 ng/mL
>2250 grams	<50 ng/mL

Biotinidase Deficiency

≥ 11 ERU Within Normal Limits
≥ 5 and ≤10 ERU Partial Deficiency
< 5 ERU Deficient

Metabolites	Normal Values	Disorder(s) Related
Amino Acid Disorders		
Citrulline	Cit < 40 μmol/L	Argininosuccinate Lyase Deficiency(Argininosuccinic Aciduria) Citrullinemia (Arginosuccinate Synthetase Deficiency)
Methionine (non-derivitized)	Met < 41 μmol/L	Homocystinuria or variant forms of Hypermethioninemia
Phenylalanine	Phe < 130 μmol/L	Phenylketonuria Hyperphenylalaninemia or other related disorders
Phe/Tyr Ratio	Phe/Tyr < 2.0 μmol/L	Phenylketonuria Hyperphenylalaninemia or other related disorders
Tyrosine	Tyr < 320 μmol/L	Transient Tyrosinemia Tyrosinemia Types I, II and III
Valine	Val < 325 μmol/L	Maple Syrup Urine Disease
Leucine	Leu < 375 μmol/L	Maple Syrup Urine Disease
Organic Acid Disorders		
C3	C3 < 6.86 μmol/L	Propionic Acidemia Methylmalonic Acidemia (MMA) Methylmalonic Acidemia w/ B12 defect and Homocystinuria Multiple CoA Carboxylase Deficiency
C4	C4 < 0.92 μmol/L	Isobutyryl CoA Dehydrogenase Deficiency (IBCD)
C4-DC	C4-DC <0.64 μmol/L	Methylmalonic Acidemia (MMA) Methylmalonic Acidemia w/ B12 defect and Homocystinuria
C5	C5 < 0.59 μmol/L	Isovaleric Acidemia (IVA) 2 Methylbutyryl CoA Dehydrogenase Deficiency (2MBCD) 2 Methyl 3 Hydroxybutyryl CoA Dehydrogenase Deficiency (2MBDH)
C5:1	C5:1 <0.05 μmol/L	2 Methyl 3 Hydroxybutyryl CoA Dehydrogenase Deficiency (2MBDH)
C5-OH	C5-OH <0.43 μmol/L	Multiple CoA Carboxylase Deficiency 2 Methyl 3 Hydroxybutyryl CoA Dehydrogenase Deficiency (2MBDH) 3 Hydroxy 3 Methylglutaryl CoA Lyase Deficiency (HMG) 3 Methyl Crotonyl CoA Carboxylase Deficiency (3 MCC) 3 Methylglutaconyl CoA Hydratase Deficiency (3MGA)
C5-DC	C5-DC <0.14 μmol/L	Glutaric Acidemia Type I (GAI)
Fatty Acid Disorders		
C4	C4 < 0.92 μmol/L	Short Chain AcylCoA Dehydrogenase Deficiency (SCAD) Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII)
C5	C5<0.51 μmol/L	Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII)
C5:1	C5:1 <0.05 μmol/L	Mitochondrial Acetoacetyl CoA Thiolase (Ketothiolase) Deficiency
C5-OH	C5-OH <0.43 μmol/L	Mitochondrial Acetoacetyl CoA Thiolase (Ketothiolase) Deficiency
C5-DC	C5-DC <0.14 μmol/L	Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII)
C6	C6< 0.16 μmol/L	Medium Chain AcylCoA Dehydrogenase Deficiency (MCAD)
C8	C8< 0.30 μmol/L	Medium Chain AcylCoA Dehydrogenase Deficiency (MCAD)
**C8/C2	C8/C2 < .10 μmol/L	Medium Chain AcylCoA Dehydrogenase Deficiency (MCAD)
C10	C10 <0.31 μmol/L	Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII)
C10:1	C10:1 <0.31 μmol/L	Medium Chain AcylCoA Dehydrogenase Deficiency (MCAD)
***C10:1/C2	C10:1/C2 < 0.09 μmol/L	Medium Chain AcylCoA Dehydrogenase Deficiency (MCAD)
C14	C14< 0.63 μmol/L	Very Long Chain AcylCoA Dehydrogenase Deficiency (VLCAD)
C14:1	C14:1 < 0.60 μmol/L	Very Long Chain AcylCoA Dehydrogenase Deficiency (VLCAD) Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII)
C14-OH	C14-OH < 0.07 μmol/L	Long Chain Hydroxyl AcylCoA Dehydrogenase Deficiency (LCHAD)
C16	C16< 7.0 μmol/L	Multiple AcylCoA Dehydrogenase Deficiency (MADD or GAII) Very Long Chain AcylCoA Dehydrogenase Deficiency (VLCAD) Long Chain Hydroxyl AcylCoA Dehydrogenase Deficiency (LCHAD) Trifunctional Protein Deficiency Carnitine/Acylcarnitine Translocase Deficiency (CACTD) Carnitine Palmitoyl Transferase Deficiency Type II
C16-OH	C16-OH < 0.06μmol/L	Long Chain Hydroxyl AcylCoA Dehydrogenase Deficiency (LCHAD) Trifunctional Protein Deficiency
C18	C18 < 1.91 μmol/L	Carnitine /Acylcarnitine Translocase Deficiency(CACTD) Carnitine Palmitoyl Transferase Deficiency Type II Long Chain Hydroxyl AcylCoA Dehydrogenase Deficiency (LCHAD) Trifunctional Protein Deficiency Very Long Chain AcylCoA Dehydrogenase Deficiency (VLCAD)
C18:1	C18:1 < 2.40 μmol/L	Carnitine /Acylcarnitine Translocase Deficiency(CACTD) Carnitine Palmitoyl Transferase Deficiency Type II
C18:2	C18:2 <1.34 μmol/L	Carnitine /Acylcarnitine Translocase Deficiency(CACTD) Carnitine Palmitoyl Transferase Deficiency Type II

VII. Specimen Criteria

Newborn Screening Laboratory personnel closely examine each specimen that arrives in the lab for quality and quantity before testing begins. Two technologists look at all unsatisfactory specimens and then a final check is made by the supervisor. The collection hospital, provider, and the infant's mother are notified by mail that a repeat specimen needs to be obtained. Unsatisfactory reports are usually mailed within 2 to 4 working days after the specimen is received. The specimens have to be recollected and sent to the laboratory which can be a costly delay if the infant is diagnosed with a genetic disorder. A satisfactory blood drop is one single drop of whole blood applied evenly and allowed to soak through the filter card and can be seen clearly with no white showing through on the other side. The spots must be large enough to allow FIVE 1/8-inch discs to be punched out with no white areas showing.

See Chart IV - 1 COMMON CAUSES OF UNSATISFACTORY NEWBORN SCREENING SPECIMENS for unsatisfactory specimen conditions and their possible causes.

Chart IV - 1
Common Causes of Unsatisfactory Newborn Screening Specimens

Unsatisfactory Specimen Conditions	POSSIBLE CAUSE
Nonuniform	Applying many small drops of blood to each circle. Applying blood with any type of capillary tube. Touching the blood drops when they are wet. Uneven soaking through the filter card is cased by exposure to moisture, glove powder touching the filter card area before collection or the use of hand creams or lotions. Contaminated surfaces with any of the above contaminants may also cause nonuniform absorption of the blood.
Filter Paper Expired	Specimen was collected on filter paper that was expired.
> 6 months	The infant was greater than 6 months of age at the time the specimen was collected.
< 24 hours	The specimen was collected before the infant was 24 hours of age.
> 5 days	The specimen was received in the laboratory greater than 5 days after the date of collection. This may be a delay in the U.S. Postal service or a delay in the hospital mail service. Mail specimens within 24 hours of collection.
Contaminated	Specimen was contaminated in some way with something like alcohol, water, formula, urine, or hand lotion for example.
Inaccurate Information	Information on the form was inaccurate or incorrect. This most often occurs when the date or time of collection is written on the form as occurring before the date and time of birth.
Incomplete Information	All blanks on the form were not filled out completely.
Quantity Not Sufficient (QNS)	The drops of blood are too small. This can be caused by improper use of the lancet or dropping blood from a capillary tube device.
Supersaturated	The drops of blood are too large. The drops of blood overlap or touch one another. The filter card is pressed against the puncture site. The blood is dropped in very large drops from a capillary tube.
Cells & Serum Separated	The usual cause is squeezing the heel during the specimen collection. It can also be caused by waiting too long for the drop of blood to form or by clotted blood. When applying blood with a capillary tube device, if the blood is not well mixed it may appear on the filter card as clotted blood.
Clotted Specimen	Clotted specimens are due to improper puncture, application with a capillary tube device, and waiting too long for a drop of blood to form allowing the blood to clot.
Altered Card	Use of a capillary tube or syringe to apply the blood can scratch the filter card when wet, or rubbing the spot when it is still wet. It can also be caused be pressing the heel to the filter card during the collection process.
Both Sides	This is from applying blood to both sides of the filter card. It is easily recognized in the lab by holding the specimen up to a light and looking at both sides for shadows.

No Blood	The form was received but there was no blood collected on the filter paper.
Heated	Specimen appears much darker than usual and appears to have been heated. Caused by too long in transit especially during the summer. Heat and humidity can affect test results. Also caused by heating a specimen to dry it.
QNSCOM	Insufficient blood to complete testing. Quantity not sufficient for test completion.
Poly Bag	Specimen received in a sealed poly bag, plastic zip lock bag, plasticene envelope, or plastic shipping bag
Detached	Blood spot filter paper detached from information portion of the card.
Accident	Laboratory Accident

VIII. Confirmation Procedures

The laboratory reports a presumptive positive result to Women's Health and Genetics (WHG) as soon as it is determined, generally within 24 to 48 hours after the specimen is received. WHG notifies the provider listed on the form by telephone and fax to initiate confirmatory testing, follow-up, and treatment of the infant. WHG also notifies the appropriate endocrinologist and Genetic Center or Sickle Cell Center. As soon as abnormal results are determined, WHG faxes or mails, by certified letter, presumptive positive results to the provider. Final results are mailed when all other test are completed, generally within 7 to 10 days after the specimen is received.

PKU Confirmation: Those infants who have an abnormal phenylalanine level on newborn screening require confirmatory testing for phenylketonuria (PKU). These infants should be referred immediately to the nearest genetic center as recommended by the Women's Health and Genetics (WHG) Follow-up Program. The genetic center will provide information regarding follow-up procedures for blood collection and mailing.

Infants who have a borderline phenylalanine level are required to have follow-up. A repeat filter-paper blood specimen should be submitted to the TDH Laboratory.

Galactosemia Confirmation: Infants who require confirmatory diagnostic testing for galactosemia should be referred immediately to the nearest genetic center for instructions regarding blood specimen collection and mailing. The WHG Follow-up Program will provide information about the nearest genetic center.

Infants with a borderline result for galactosemia are required to have a repeat filter-paper blood specimen sent as soon as possible to the TDH Laboratory.

Infants who received a transfusion before the newborn screening test need to have a repeat filter-paper blood specimen collected ten days following the last date of transfusion and within three days of lactose feedings. Repeat galactosemia screening is done again three months after the transfusion.

Hemoglobinopathy Confirmation: All infants either transfused or whose initial screen identified an abnormal hemoglobin trait or disease must have a hemoglobin confirmation performed by the Meharry Sickle Cell Center. All supplies, including mailers, collection devices, and forms can be ordered from:

Comprehensive Sickle Cell Center
Meharry Medical College
Nashville, TN 37208

Telephone: (615) 327-6763

Congenital Hypothyroidism Confirmation: WHG will notify the provider of infants who require confirmatory diagnostic thyroid testing. WHG recommends serum thyroid testing for confirmatory testing. This may be handled by the primary care physician or an endocrinologist.

Congenital Adrenal Hyperplasia (CAH) Confirmation: Infants who require confirmatory diagnostic testing for CAH should be referred immediately to the nearest pediatric endocrinologist for instructions regarding blood specimen collection and follow-up.

Biotinidase Deficiency Confirmation: Those infants who have a deficient Biotinidase level on newborn screening require confirmatory testing for Biotinidase. These infants should be referred immediately to the nearest genetic center as recommended by the Women's Health and Genetics(WHG) Follow-up Program. The genetic center will provide information regarding follow-up procedures for blood collection and mailing.

Infants who have a partial deficiency biotinidase level are required to have follow-up. A repeat filter-paper blood specimen should be submitted to the TDH Laboratory.

Amino Acid Disorder Confirmation: Infants who have an elevated amino acid level(s) are required to have follow-up. The genetic center will provide information regarding follow-up procedures for blood collection and mailing.

Organic Acid Disease Disorder Confirmation: Infants who have elevated organic acid level(s) are required to have follow-up. The genetic center will provide information regarding follow-up procedures for blood collection and mailing.

Fatty Acid Oxidation Disorders Confirmation: Infants who have an elevated Fatty acid level(s) are required to have follow-up. The genetic center will provide information regarding follow-up procedures for blood collection and mailing.

IX. Material for Parents

The state provides pamphlets for parents to educate them about the Newborn Screening Test. These yellow pamphlets can be obtained from Women's Health and Genetics(WHG) by calling (615) 262-6304. The pamphlet answers questions most often asked and explains briefly the 5 disorders and how the testing is done.

There is also a green pamphlet "Your Baby Needs to be Rescreened" which is require by state law to be given to every parent whose infant leaves the hospital before 24 hours of age. You are still required to do a newborn screen on this infant before he/she leaves. On newborn screenings done before the infant is 24 hours old, only the Hemoglobin test is accurate, the other test will have to be repeated within 2 weeks. The green pamphlet explains this to the parents and also gives an overview of the 4 disorders the infant will need to be retested for.

X. Infant Discharged before Specimen Was Obtained

When the nursery or lab forgets to get a specimen on an infant before he/she leaves, we ask that you still send in a newborn screening collection form completely filled in and write, "LEFT BEFORE OBTAINED" on the form. You are responsible for notifying the parent and the physician of the need for the test. Newborn Screening will also contact the physician and make sure the infant is screened. When collection forms for these infants are not sent in, we are unaware that the infant exists.

XI. Refusal to Have Newborn Screening Performed

When a parent refuses the newborn screening test, we ask that you do send in a newborn screening collection form completely filled in and write "REFUSED" on the form, and we will follow up. If a parent refuses the test due to religious reasons, please fill out the NEWBORN SCREENING REFUSAL FORM (See Page IV - 25), have it notarized, and fax it to Women's Health and Genetics at (615) 262-6458.

XII. Death Notice

If you are aware of an infant that has expired, please fax us the child's name, date of birth, mothers name, and the date the infant expired. If a specimen needs to be repeated we will continue to send letters to the mother until we receive a specimen. In this case, we do NOT want to notify the parent. Maternal and Child Health's fax number is (615) 262-6458.

XIII. Specimen Collection for the Hemoglobin Electrophoresis Procedure from Meharry Sickle Cell Center

Proper collection and handling of specimens are essential when sending samples to the Meharry Sickle Cell Center. The following steps must be adhered to so specimens are not damaged in transit and comply with Occupational Safety and Health Administration (OSHA) standards and postal regulations. If these directions are not followed, your samples may not reach us. Your cooperation in this matter is appreciated.

Supplies Needed: Request form (Adult/Children), Microvette Tube EDTA, Plastic Biohazard Bags, Styrofoam Mailing Boxes, and Packing Tape.

Each Microvette tube contains enough EDTA to anticoagulant up to 200 µl of blood.
Note special instructions in tube package.

1. Label the Microvette tube with the patient's name (label not included).

2. Perform a heel stick using good laboratory practice and following the instructions of the lancet device manufacturer.

3. Wipe off the first drop of blood. Then touch the capillary tip of the Microvette Tube to the droplet of blood as it appears at the incision. Excessive pressure or squeezing on puncture area must be avoided. This could lead to premature coagulation in the capillary.

4. After the blood has been taken, the capillary unit is removed and properly discarded and the sample container is closed with the attached stopper.

5. Properly mix the blood with the EDTA. Hold the stoppered collection Microvette Tube between thumb and index finger and invert several times.

6. Complete the laboratory request form with all information. Include the address to send results. Fold the laboratory request form and place it in the unsealed pocked of a biohazard bag.

7. Place the sealed Microvette Tube in the ziplock pocket of the biohazard bag and place into a Styrofoam mailing box.

8. Place the Styrofoam box in the mailing sleeve and seal both ends. Please put the return address on the mailing box.

9. Mail appropriately packaged sample(s) to :

ATTN: Laboratory Supervisor
Comprehensive Sickle Cell Center
Meharry Medical College
1005 D. B. Todd Boulevard
Nashville, Tennessee 37208

Phone (615) 327-6763 Fax (615) 327-6008

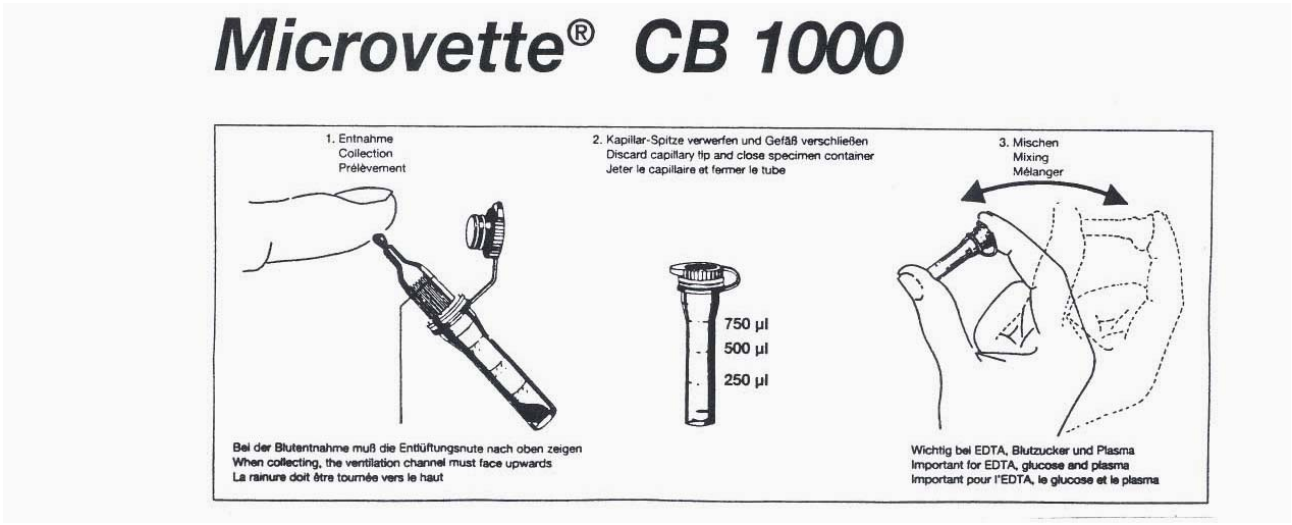

Microvette® CB 1000
1. Entnahme
Collection
Prélèvement
2. Kapillar-Spitze verwerfen und Gefäß verschließen
Discard capillary tip and close specimen container
Jeter le capillaire et fermer le tube
3. Mischen
Mixing
Mélanger
750 µl
500 µl
250 µl
Bei der Blutentnahme muß die Entlüftungsnute nach oben zeigen
When collecting, the ventilation channel must face upwards
La rainure doit être tournée vers le haut
Wichtig bei EDTA, Blutzucker und Plasma
Important for EDTA, glucose and plasma
Important pour l'EDTA, le glucose et le plasma

Chart IV - 2
Pounds and Ounces to Grams Conversion

1 Kilo = 1000 grams

Example: To obtain grams equivalent to 5 pounds, 8 ounces, read "5" on the top scale, and read "8" on the side scale; it is equivalent to 2495 grams.

		POUNDS														
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	0	0	454	907	1361	1814	2268	2722	3175	3629	4082	4536	4990	5443	5897	6350
	1	25	482	936	1389	1843	2295	2750	3203	3657	4111	4584	5018	5471	5925	6379
	2	57	610	964	1417	1871	2325	2778	3232	3686	4139	4593	5046	5500	5953	6407
	3	85	639	992	1448	1899	2353	2807	3260	3714	4157	4621	5075	5528	5982	6435
	4	113	687	1021	1474	1928	2381	2835	3289	3742	4196	4649	5103	5557	6010	6464
OUNCES	5	142	695	1049	1503	1958	2410	2863	3317	3770	4224	4675	5131	5585	6038	6492
	6	170	625	1077	1531	1964	2438	2882	3345	3799	4252	4706	5168	5613	6067	6520
	7	198	652	1108	1559	2013	2466	2920	3374	3827	4281	4734	5188	5642	6095	6549
	8	227	680	1134	1588	2041	2495	2948	3402	3856	4308	4763	5210	5670	6123	6577
	9	255	709	1162	1616	2070	2523	2977	3430	3884	4337	4791	5245	5698	6152	6605
	10	283	737	1191	1644	2098	2551	3005	3459	3912	4366	4819	5273	5727	6180	6631
	11	312	765	1210	1673	2126	2580	3033	3487	3941	4394	4848	5301	5765	6209	6662
	12	340	784	1247	1701	2155	2608	3062	3515	3969	4423	4876	5330	5783	6237	6690
	13	369	822	1278	1729	2183	2637	3090	3544	3997	4451	4904	5358	5812	6265	6719
	14	397	850	1304	1758	2211	2665	3118	3572	4026	4479	4933	5366	5840	6294	6747
	15	425	879	1332	1786	2240	2693	3147	3600	4054	4506	4961	5415	5868	6322	6776

NOTE: 1 pound = 453.59237 grams;
1 ounce = 28.349523 grams;
1000 grams = 1 kilogram.

Gram equivalents have been rounded to whole number by adding one when the first decimal place is 5 or greater.

Chart IV - 3
Military Time Conversion Chart

CIVILIAN TIME		MILITARY TIME
1:00 AM		0100
2:00 AM		0200
3:00 AM		0300
4:00 AM		0400
5:00 AM		0500
6:00 AM		0600
7:00 AM		0700
8:00 AM		0800
9:00 AM		0900
10:00 AM		1000
11:00 AM		1100
12:00 a.m. noon		1200
1:00 PM		1300
2:00 PM		1400
3:00 PM		1500
4:00 PM		1600
5:00 PM		1700
6:00 PM		1800
7:00 PM		1900
8:00 PM		2000
9:00 PM		2100
10:00 PM		2200
11:00 PM		2300
12:00 p.m. midnight		2400

An infant born at 12:05 AM or 5 minutes after midnight would be written as 0005 military time.

Newborn Screening (Continued)

Chart IV - 4

TENNESSEE COUNTY CODE LIST

COUNTY CODE	COUNTY NAME		COUNTY CODE	COUNTY NAME
01	ANDERSON		49	LAUDERDALE
02	BEDFORD		50	LAWRENCE
03	BENTON		51	LEWIS
04	BLEDSOE		52	LINCOLN
05	BLOUNT		53	LOUDON
06	BRADLEY		54	MCMINN
07	CAMPBELL		55	MCNAIRY
08	CANNON		56	MACON
09	CARROLL		57	MASIDON
10	CARTER		58	MARION
11	CHEATHAM		59	MARSHALL
12	CHESTER		60	MAURY
13	CLAIBORNE		61	MEIGS
14	CLAY		62	MONROE
15	COCKE		63	MONTGOMERY
16	COFFEE		64	MOORE
17	CROCKETT		65	MORGAN
18	CUMBERLAND		66	OBION
19	DAVIDSON		67	OVERTON
20	DECATUR		68	PERRY
21	DEKALB		69	PICKETT
22	DICKSON		70	POLK
23	DYER		71	PUTNAM
24	FAYETTE		72	RHEA
25	FENTRESS		73	ROAN
26	FRANKLIN		74	ROBERTSON
27	GIBSON		75	RUTHERFORD
28	GILES		76	SCOTT
29	GRAINGER		77	SEQUATCHIE
30	GREENE		78	SEVIER
31	GRUNDY		79	SHELBY
32	HAMBLEN		80	SMITH
33	HAMILTON		81	STEWART
34	HANCOCK		82	SULLIVAN
35	HARDEMAN		83	SUMNER
36	HARDIN		84	TIPTON
37	HAWKINS		85	TROUSDALE
38	HAYWOOD		86	UNICOI
39	HENDERSON		87	UNION
40	HENRY		88	VAN BUREN
41	HICKMAN		89	WARREN
42	HOUSTON		90	WASHINGTON
43	HUMPHREYS		91	WAYNE
44	JACKSON		92	WEAKLY
45	JEFFERSON		93	WHITE
46	JOHNSON		94	WILLIAMSON
47	KNOX		95	WILSON
48	LAKE			

Patient's Name _____
Mother's Name _____
Date of Birth _____
Hospital of Birth _____

NEWBORN SCREENING REFUSAL

I, _____ have been informed of the need for newborn screening which includes testing for phenylketonuria (PKU), congenital hypothyroidism, congenital adrenal hyperplasia, galactosemia, hemoglobinopathies, and other metabolic/genetic defects that would result in mental retardation or physical dysfunction as determined by the health department.

I have been informed that state law requires this testing and that violation of the law is a misdemeanor.

Nonetheless, I refuse these tests at this time for my newborn baby _____ because such test conflicts with my religious tenets and practices.

Under penalty of perjury, I affirm such refusal because of a conflict with my religious tenets and practices.

IN WITNESS WHEREOF, the undersigned has signed this form this _____ day of _____, 2_____.

_____
Signature

STATE OF TENNESSEE

COUNTY OF _____

On this _____ day of _____, 2_____, before me personally appeared _____, to me known (or proved to me on the basis of satisfactory evidence) to be the person described in and who executed the foregoing instrument, and acknowledged that she executed the same as her own free act and deed.

_____
Notary Public

My Commission Expires:

_____
REFUSAL

REQUEST FOR RELEASE OF RECORDS

Baby's Last Name _____

Baby's First Name _____

Date of Birth _____

Mother's Last Name _____

Mother's First Name _____

Mother's Social Security Number_____

Hospital of Birth or Collection _____

Any other previous last names used by the mother or the baby:
_____

Name of Contact person in provider's office: _____

Direct Phone number of Contact Person: _(_____)_____

In the event we have trouble locating the baby listed above we will attempt to contact the provider for additional information.

I, _____ the legal parent or guardian of the baby listed above do hereby give consent for the State of Tennessee Newborn Screening Laboratory to release results to the Physician or Group Listed here_____.

_____
Parent's Signature

_____
Witness's Signature

MEMORANDUM

TO: Submitters/Providers of Newborn Screening Specimens
FROM: Michael W. Kimberly, Dr PH, MPH, HCLD
DATE: January 19, 2005
SUBJECT: **Newborn Screening Update: Change in accepting specimens from transfused infants**

Newborn Screening can be affected by transfusion of a newborn prior to collection of the blood sample. Laboratory Services' transfusion protocol was to request a repeat filter paper, if the date of collection for the blood specimen was less than four days post transfusion for TSH and 17 OHP and less than ten days post transfusion for Tandem Mass Spectrometry, Galactose and Biotinidase. Hemoglobinopathies required recollection three months post transfusion.

On January 13, 2005 the State Laboratory changed this protocol based on the recommendation of the Genetic Advisory Committee. We will require a recollection of the filter paper, if the date of collection is less than four days post-transfusion for all tests except Hemoglobinopathies. Hemoglobinopathies will remain the same at three months. If you should have any questions, please call the Newborn Screening Laboratory at 615-262-6352 or the Follow-up Program at 615-262-6304.

TENNESSEE DEPARTMENT OF HEALTH - LABORATORY SERVICES
REQUISITION FOR LABORATORY SUPPLIES

SEND TO _____

ADDRESS _____

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SIGNATURE _____ PHONE _____

***** SUBMIT THIS FORM TO THE LABORATORY. BE SPECIFIC IN ORDERING. *****

Quantity	**COMPLETE KITS (Includes Form, Mailing Label, and Mailer)**	**REQUEST FORMS**	
	TB smear and culture	Miscellaneous Examination PH-1573	
	Intestinal Parasites (O&P)	Water Bacteriology Analysis PH-1575	
	Pinworm	Mycobacteriology Smear and Culture	
	Pertussis	PH-1577	
	Water Bacteriology	Syphilis Serology PH-1578	
	Foodborne Outbreak Stool Collection Kit	Virology PH-1579	
INDIVIDUAL ITEMS		Req. Laboratory Supplies PH-1580A	
(Includes All Supplies Except Forms and Mailers)		Newborn Screening PH-1582	
	Cary-Blair for Enteric/Bacterial Transport	***(Order From Nashville Only)***	
	Chlamydia/Gonorrhea Female Collection Kit	Gonococcus Culture PH-1583	
	Chlamydia/Gonorrhea Male Collection Kit	Rabies PH-1584	
	Gonorrhea Culture	Group A Streptococcus PH-1587	
	Throat Cultures for Group A Strep (TSA)	Immunoserology PH-1589	
	Vacutainer Tubes (7ml draw)	Rubella Serology PH-1917	
	Viral Transport Media (1.5 ml. / tube)	HIV-1 Serology PH-3173	
	Diphtheria (Pai) ***(Order From Nashville Only)***	Chlamydia and Gonorrhea Detection	
	Charcoal Agar (For Pertussis Only)	PH-3179	

MAILING CONTAINERS		**MAILING LABELS**	
	Medium (1-3 tubes, single bloods)	GONO-PAK	
	Large (3-6 tubes, multi-bloods, GC Culture)	MYCO	
		Specimen For Microbiological Examination	
		PH-0838	

SPECIAL NEEDS _____

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ORDERING INFORMATION

- Please order only what you will use in one month
- Please submit order one week in advance of need
- Be sure to check expiration dates carefully
- Please return all incomplete or expired materials

THREE EASY WAYS TO ORDER

1. Mail to: Tennessee Department of Health
   Laboratory Services
   630 Hart Lane
   Nashville, Tennessee 37247-0801
2. FAX (615) 262-6393
3. Call (615) 262-6322

FOR LABORATORY USE ONLY

RECEIVED _____ Date FILLED _____ Date INITIALS _____ SHIPPED _____ Date

PH-1580A RDA
1160 REV 8/00